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February 25, 2019

VIA FACSIMILE AND E-MAIL
Daniel C. Burke, Esq.
Bernstein Liebhard, LLP
10 East 40th Street
New York, NY 10016

Re: *Sabol v. Bayer HealthCare Pharmaceuticals, Inc., et al.*
Civil Action No. 1:18-cv-11169

Dear Mr. Burke:

Pursuant to the Honorable Victor Marrero's Individual Rules, Defendants GE Healthcare Inc. and General Electric Company (collectively, "GEHC") submit this letter regarding Plaintiff Marcia Sabol ("Plaintiff") setting forth the grounds upon which the Court should dismiss Plaintiff's Complaint ("Complaint") under Federal Rule of Procedure 12(b)(6).

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a plaintiff's complaint "must contain sufficient factual matter, accepted as true, to state claim to relief that is plausible on its face." *Icahn Sch. of Med. at Mount Sinai v. Neurocrine Biosciences, Inc.*, 191 F. Supp. 3d 322, 328 (S.D.N.Y. 2016) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiff's claims fails to meet the standards required by Rule 12(b)(6) for the reasons set forth below.

I. PLAINTIFF ALLEGES ONLY CONCLUSORY ALLEGATIONS

Plaintiff alleges she received injections of gadolinium-based contrast agents ("GBCA"), including Omniscan. As a result of her injections, she raises two claims against Defendants: (1) strict product liability - failure to warn and (2) negligence. "Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent." *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 439–40 (S.D.N.Y. 1999). "A manufacturer has a duty to

warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known." *Id.* (internal citation omitted). To state a prima facie claim for failure to warn, "[a] plaintiff must demonstrate [1] that the warning was inadequate and [2] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." *Chandler v. Janssen Pharm., Inc.*, 322 F. Supp. 3d 314, 322–23 (E.D.N.Y. 2018) (internal citation omitted).

Plaintiff's failure-to-warn claims are premised upon little more than conclusory allegations. For example, Plaintiff's negligence claim states that GEHC "breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled [Omniscan]." (Compl. ¶ 110). Plaintiff further alleges that Omniscan was promoted in "an overly aggressive, deceitful, and fraudulent manner" and, yet, does not provide any factual allegations to show how Omniscan was marketed to Plaintiff, what her healthcare providers said about the product, or the risks she was aware of. (*See id.* at ¶ 111(d).)

Further, Plaintiff does not link any defect in the manufacture, design, or warnings that accompanied Omniscan with her own injuries. Plaintiff further suggests that macrocyclic GBCAs are a safer alternative, without providing any facts to show how a macrocyclic GBCA would have not caused her alleged symptoms. (*See id.* at ¶¶ 51, 60.) Plaintiff also does not state the risks of using macrocyclic agents nor that, if available to her, she would have chosen a macrocylic agent instead of Omniscan. GEHC requires sufficient factual detail of Plaintiff's claims in order to "adequately prepare a defense." *See Twombly*, 550 U.S. at 555.

II. PLAINTIFF ALLEGES NO SPECIFIC INJURY AND THEREFORE HAS NOT ALLEGED ANY CAUSATION

For causation, a plaintiff must prove both general and specific causation. *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 251 n.1 (2d Cir. 2005). "General causation bears on whether the type of injury at issue can be caused or exacerbated by the defendant's product. 'Specific' causation bears on whether, in the particular instance, the injury actually was caused or exacerbated by the defendant's product." *Id.* Plaintiff's Complaint does not include specific allegations related to general or specific causation, so her claims must fail.

Plaintiff does not and cannot allege any disease caused by Omniscan for which Plaintiff is at risk. Plaintiff admits she had normal renal function, and thus cannot have Nephrogenic Systemic Fibrosis, a recognized disease for individuals with impaired kidney function. (*See* Compl. at ¶ 18.) Rather, because GBCAs are associated with a distinct disease in a distinct population that does not include Plaintiff, Plaintiff attempts to bootstrap her claims here by alleging the existence of an unnamed "disease that [is] associated with gadolinium other than NSF." (*Id.* at ¶ 74.) No such "disease" has not been accepted by the FDA or the relevant medical community. Indeed, they have rejected any evidence of association. This is particularly true in light of the FDA's recent statement on the safety of gadolinium. "**Gadolinium retention has not been linked to adverse health effects in patients with normal kidney function, and we have concluded that the benefit of all approved GBCAs continues to outweigh any potential**

risks."[1] Given that the FDA has expressly rejected the premise of any association, let alone a causal link, between gadolinium retention and any alleged resulting disease process, Plaintiff has not and cannot plead substantial facts in support of her claims.

Plaintiff also does not allege any facts to support specific causation. *See Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 151 (S.D.N.Y. 2012) ("A plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or her injuries."); *Nealy v. U.S. Surgical Corp.*, 587 F. Supp. 2d 579, 583 (S.D.N.Y. 2008) ("Causation is an essential element of any negligence claim"). Here, Plaintiff simply claims: (1) she received a gadolinium-based contrast agent, Omniscan, (2) she allegedly suffers from an unnamed "disease that [is] associated with gadolinium other than NSF," and (3) studies have observed that gadolinium can be retained in the body. (*See* Compl. ¶¶ 16, 74, and 75.) Plaintiff does not allege any actual injury, objective medical symptoms, or medical diagnosis resulting from this alleged retention. (*See id.* at ¶ 16.)

Even if Plaintiff adequately pled her failure-to-warn claims, New York courts apply the learned intermediary doctrine on such claims in the context of prescription drugs. "Under the learned intermediary doctrine, the duty to warn runs from the drug manufacturer to the treating physician—not the patient." *In re Fosamax Prod. Liab. Litig.*, 688 F. Supp. 2d 259, 265 (S.D.N.Y. 2010) (internal citation omitted). "The causation inquiry therefore focuses on the hypothetical actions of Plaintiff's treating physician had he been provided a proper warning." *Id.* As a result, if Plaintiff's physician prescribed Omniscan using his or her medical judgment, Plaintiff cannot recover unless her physician would have prescribed a different product based on an alternative warning. *See id.* Plaintiff makes no such allegations. Further, the FDA has instituted class labeling for all GBCAs, making any such claim by Plaintiff impossible. Thus, this Court should dismiss Plaintiff's strict liability and negligence claims.

Plaintiff's claims are unclear and unsupported by any well-pleaded facts, as Plaintiff instead relies primarily on conclusory allegations. For the foregoing reasons, GEHC will request that the Court grant its forthcoming Rule 12(b)(6) motion to dismiss.

The Clerk of Court is directed to enter into the public record of this action the letter above submitted to the Court by GEHC defendants described above.

SO ORDERED.

2-25-19
DATE

VICTOR MARRERO, U.S.D.J.

Very truly yours,

STEPHEN G. TRAFLET

cc: The Honorable Victor Marrero (via facsimile)
All Counsel of Record (By Email)

[1] U.S. Food & Drug Administration, *FDA Drug Safety Communication: FDA warns that gadolinium-based contrast agents (GBCAs) are retained in the body; requires new class warnings*, Dec. 19, 2017, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm (last visited Feb. 19, 2018) (emphasis added).